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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/613,443

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EXAMINER

POUS, NATALIE R

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

01/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,443

Applicant(s)

GOLDFARB ET AL.

Examiner

Natalie Pous

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-24 and 60-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-19, 21-24, 60-66, 69 and 71 is/are rejected.
- 7) ☒ Claim(s) 20, 67, 68 and 70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/2/06, 2/13/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claim 13-24 and 60-66 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claims 68 and 69 are objected to because of the following informalities: claims 68 and 69 depend from canceled claim 1, however it is inferred that the proper dependency is from claim 21. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-19, 21-24, 60- 66, 69, 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. (US 6117159) in view of Laufer et al. (US 5810847). Huebsch teaches an apparatus capable of repairing a valve in a patient's body, the valve having a plurality of movable leaflets, the leaflets having a superior surface on a first side and an inferior surface on an opposing side, the apparatus comprising:

- a pair of articulating arms (24) coupled together and movable from an open position in which portions of the articulating arms are spaced apart (proximal-most and distal-most portions of arm 24, fig. 2) to a closed position in which the portions of the arms are closer together (fig. 4),
- said arms being configured to engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration (fig. 5a) wherein the arms are implantable in the patient's body to maintain the leaflets in the coapted configuration (fig. 5a);
- a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms, wherein the arms can be closed to engage the leaflets and thereafter be opened to allow release of the leaflets (claim 7)
- the apparatus further comprising a central member (18), the arms being movably coupled to the central member
- wherein the articulating arms (24) are configured to clamp the leaflets between the articulating arms and the central member in the closed position

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- wherein the central member is configured to be positioned through the valve between the leaflets (fig. 5a, it is noted that the device is configured for use in the heart and is of a size which is configured for used in the valve leaflets).
- wherein the central member (18) is detachably coupled to a shaft (148) adapted for delivering the arms into the heart.
- A pair of superior elements (22) movably coupled to the central member (18), the superior elements being configured to engage the superior surfaces whereby the leaflets may be pinched between the articulating arms and the superior elements (fig. 5a)
- Wherein the superior elements (22) are coupled to a conduit (16) slidably coupled to the central member (18)
- wherein the articulating arms (24) have engaging surfaces capable of engaging the surfaces of the leaflets
- wherein the engaging surfaces have texture or teeth (70) for enhancing friction
- wherein the shaft (148) is flexible and configured for positioning through a blood vessel to the heart (fig. 5b)
- wherein the shaft (148), articulating arms (24) and central member (18) are slidably positionable through an endovascular sheath (40, fig. 5a)
- wherein the arms engage the surfaces without penetration thereof (fig. 5a)
- wherein the articulating arms and superior elements are slidably positionable through a blood vessel (64) into the heart

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- wherein the control mechanism is adapted to open and close the pair of articulating arms in tandem (figs. 2-4)

Huebsch fails to teach wherein the device is capable of holding the leaflets such that portions of the superior surfaces are facing each other. It would have been an obvious matter of design choice to provide the device of Huebsch such that it is capable of holding the leaflets such that portions of the superior surfaces are facing each other as taught by Laufer, since applicant has not disclosed that such a feature provides any advantage over holding the portions such that they are simply in line with each other, and it appears that the device of Huebsch performs the task of holding two portions of the heart in a coapted configuration equally well as that of the disclosed application, and it is known to hold valve leaflets in a coapted configuration wherein portions of the superior surfaces of the leaflets are facing each other.

Allowable Subject Matter

Claims 18, 67, 68 and 70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
12/18/06


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

12/24/06.